K043406

PREMARKET NOTIFICATION [510(k)] SUMMARY

JUL 15 2005

Trade Name: Vertebroplastic™ Radiopaque Bone Cement

Common Name: Polymethylmethacrylate (PMMA) bone cement

Classification Name: Filler bone cement (for vertebroplasty)

Regulatory Class: Class II, per 21 CFR §888.3027,

Device Code: NDN

510k Sponser:
DePuy Spine, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Manufacturer:
DePuy International Limited, trading as
DePuy CMW
Cornford Road
Blackpool
Lancashire FY4 4QQ
United Kingdom

Contact Person:
Sharon Starowicz,
Director of Regulatory Affairs
DePuy Spine, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350
Tel.: (508) 828-2867; Fax: (508) 828-3797

Equivalent to:
KyphX® HV-R™ Bone Cement Model C01A (K041584)

Stryker SpinePlex™ Radiopaque Bone Cement (K032945)

Stryker Howmedica Surgical Simplex® P Radiopaque pre-packed in ACM and MixEvac II (K002652)

Cranioplastic™, acrylic cranioplasty material (K873689)

Device Description: Vertebroplastic™ Radiopaque Bone Cement is a self-curing, radiopaque, polymethylmethacrylate (PMMA) cement, for filling of spinal vertebral body defects, in order to provide stabilization of the vertebral body and pain relief. Vertebroplastic™ Radiopaque Bone Cement has a low viscosity and long working and setting time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2005

Ms. Sharon Starowicz
Director of Regulatory Affairs
DePuy Spine, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K043406
Trade Name: Vertebroplastic Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Bone Cement for Vertebroplasty
Regulatory Class: II
Product Code: NDN
Dated: June 8, 2005
Received: June 9, 2005

Dear Ms. Starowicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

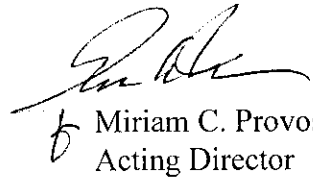
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Vertebroplastic™ Radiopaque Bone Cement

Indications for Use:

Vertebroplastic™ Radiopaque Bone Cement is indicated for the treatment, using vertebroplasty or kyphoplasty procedures, of pathological fractures of the vertebral body caused by osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K043406